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## Notice of Allowability

Application No.

10/018,453

Examiner

Frank W. Lu

Applicant(s)

ZABEAU ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/6/2004.
2. ☒ The allowed claim(s) is/are 57-96,99,100,102 and 104-114.
3. ☒ The drawings filed on 30 October 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 3/7/2005.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

## **DETAILED ACTION**

### ***Reasons for Allowance***

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Nabeela McMillian (Reg. No. 43,363) on March 7, 2005.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I, claims 57-99 and 104-107, species (1) (an eukaryotic transcription control sequence, claim 63), species 4 (the modification consists of a 2'-deoxy, 2'-O-methyl, 2'-fluoro or 2'-amino substituent on the nucleotide triphosphates, claim 69), species (8) (the complementary cleavage reaction is enzymatic cleavage, claims 75 and 78-80), species (11) (the one or more target nucleic acids are phosphorothioate-modified single stranded DNA or RNA, and wherein the cleavage reactions are performed with the nuclease P1, claim 81), and species (15) (said four RNase-specific cleavage reactions comprise RNase T1 and RNase U2 cleavage of the + and -strands of said target nucleic acid, claim 106) in the reply filed on December 6, 2004 is acknowledged. The traversal is on the ground(s) that: (1) Applicants respectfully submit that the reasons recited in Restriction are not directed to the different uses of the product but merely recite uses for the individual components of the kits; and (2) "the Applicants respectfully must point out that it is not those individual components that are the

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‘product’ identified by the Examiner or being claimed by the Applicants. The claims of group II of the invention are directed to kits. This ‘product’ contains triphosphates, polymerases, nucleic acid cleaving agents, reference nucleic acids, reagents for purification of PCR products, ion exchange beads, a solid support for use in mass spectrometry and a computer software program. Please note that the steps (a) through (h) of claim 100 are not alternative uses (as would be implied by the Examiner's rejection) but are rather separate components of the mass spectrometry kit. So again Applicants clarify that the ‘product’ is the mass spectrometry ‘kit’ not the individual components of the kit. For this reason, Applicants submit that the restriction is not proper and should be vacated”; and (3) “[T]he novelty and non-obviousness of the invention lies in the steps of the that demonstrate the use of mass spectrometry of non-ordered fragments generated from multiple cleavage reactions to deduce the sequence of a given target nucleic acid. Therefore, the specific control sequence (claims 63 and 64), the type of modified nucleotide triphosphate (claims 69, 70, 71, 72); the type of cleavage reaction (claims 75 and 77-80); or the nature of the target nucleic acid (claims 81, 82, 83, or 84) the type of RNase used (claims 106 and 107) is not the defining feature of the invention”.

The above arguments have been fully considered. Since the examiner notes that this instant case is 371 case and there is no 102 type of art against any product claim, the examiner agrees to combine Groups I and II together and all species together. Therefore, claims 57-96, 99, 100, 102, and 104-114 will be examined and the restriction has been withdrawn.

3. Application has been amended as follows:

In the specification: add following “abstract” to the last page of the specification

Abstract

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The present invention is in the field of nucleic acid-based diagnostic assays. More particularly, it relates to methods useful for the “diagnostic sequencing” of regions of sample nucleic acids for which a prototypic or reference sequence is already available (also referred to as “re-sequencing”), or which may be determined using the methods described herein. This diagnostic technology is useful in areas that require such re-sequencing in a rapid and reliable way: (i) the identification of the various allelic sequences of a certain region/gene, (ii) the scoring of disease-associated mutations, (iii) the detection of somatic variations, (iv) studies in the field of molecular evolution, (v) the determination of the nucleic acid sequences of prokaryotic and eukaryotic genomes, (vi) identifying one or more nucleic acids in one or more biological samples', (vii) and determining the expression profile of genes in a biological sample and other areas.

In the claims:

Replace “to analyse the sequence of said target nucleic acid” in step (d) of claim 57 with --- and sequencing said target nucleic acid ---.

Delete “57” in line 2 of claim 100.

Replace “A kit” in line 1 of claim 112 with ---The kit ---.

Delete “and” after the phrase “one or more RNAses” in (c) of claim 114.

Add the phrase “ and (e) a computer software for analysing the mass spectra of the sequence of said target nucleic acid resulting in one or more unique sequences” after the phrase “whereon the non-ordered set of fragments may be spotted” in claim 114.

4. The following is an examiner's statement of reasons for allowance:

Claims 57-96, 99, 100, 102, and 104-114 are allowable in light of the applicant's amendments filed on March 26, 2004 and the examiner's amendment. The closest prior art in the record are Koster (WO 96/29431, published on September 26, 1996) and New England Biolabs Catalog (page 74, 1996-1997). Note that fragments generated by one or more restriction enzymes can not considered as non-ordered set of fragments as recited in claim 57. Koster does not teach a non-ordered set of fragments generated by two or more cleavage reactions (see applicant's remarks filed on March 26, 2004, page 16, first paragraph) recited in claim 57 while New England Biolabs Catalog does not teach a computer software for analysis of mass spectra (see applicant's remarks filed on March 26, 2004, page 23, fourth paragraph) as recited in claims 100, 102, and 114. These prior art either alone or in combination with the other art in the record do not teach or reasonably suggest a method for sequencing one or more target nucleic acids present in one or more biological samples and kits which comprise all of the limitations recited in claims 57, 100, 102, and 114.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

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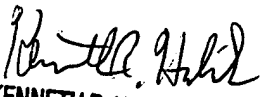
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu  
PSA  
March 7, 2005

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
3/7/05